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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,812	05/08/2007	Hiroshi Kanai	NIHE-40596	1931

52054 7590 08/23/2010  
PEARNE & GORDON LLP  
1801 EAST 9TH STREET  
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CLEVELAND, OH 44114-3108

EXAMINER
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FONTENOT, NIGEL RAI

ART UNIT	PAPER NUMBER
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3768

NOTIFICATION DATE	DELIVERY MODE
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08/23/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@pearne.com  
dchervenak@pearne.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,812	<b>Applicant(s)</b> KANAI ET AL.	
	<b>Examiner</b> NIGEL FONTENOT	<b>Art Unit</b> 3768	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/7/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is responsive to the Amendments/Arguments filed 7/7/2010. Claims 1-2 and 5-12 have been amended. Claims 1-12 are still pending.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (US 5830131), in view of Hasegawa et al. (Evaluation of Regional Elastic modulus of Cylindrical Shell with Nonuniform Wall thickness).

4. Addressing claims 1-12, Caro discloses an ultrasonic diagnostic method and apparatus for diagnosing vascular endothelial function by using an ultrasonic diagnostic apparatus (see col. 3 lines 14-40), comprising a transmitter/receiver for transmitting and

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receiving ultrasonic waves (see col. 22 lines 22-45), a phase detector for detecting a phase of the received ultrasonic echo (see fig. 5, col. 22 lines 22-45, and col. 23 lines 18-40; a phase is necessarily detected), and an arithmetic unit for calculating elastic modulus of vascular wall based on an ultrasonic echo obtained through phase detection (see col. 23 lines 18-40, the modulus is calculated based an echo that includes a phase), wherein said method comprising: a step (A) of transmitting ultrasonic waves into tissues of living body including vascular wall, and receiving an ultrasonic echo obtained when said ultrasonic waves is reflected and scattered by said vascular wall, said vascular wall having a thickness (see col. 22 lines 22-45); a step (B) of detecting a phase of said ultrasonic echo (see col. 22 lines 22-45; a phase is necessarily detected); and of determining elastic modulus of said vascular wall from a thickness change and a blood pressure value (see col. 23 lines 18-40; the tunica intima and tunica media are included in the vascular wall). Caro discloses that the elastic modulus of said vascular wall comes from the thickness of the wall (see col. 23 lines 20-40). Caro discloses a piezoelectric sensor that senses arterial wall displacement and position (see col. 7 lines 9-17), discloses that the phase of the waveform corresponds to the blood pressure for many frequencies and is predictable based on this relationship (see col. 10 lines 42-62), and that the thickness of a vessel, modulus, or the vessel radius can change over time. Caro discloses that the thickness of a vessel, modulus, or the vessel radius can change over time including when blood is flowing through it and there is need to optimize treatments based on these parameters (see col. 23 lines 18-40). Hasegawa discloses that a vessel changes thickness in a pulsatile fashion. To measure this thickness, a

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vibration velocity is measured first by measuring the phase shift between the ultrasonic pulses. Then the vibration velocity is measured for the inner and outer surface uses this to find the change in thickness as a function of time over a period of time. Hasegawa discloses that if plaque is in the vessel, then the vessel is not a perfect cylinder, so more calculation is needed. The vessel thickness is divided into layers and the modulus is calculated corresponding to each layer thickness. Thus the modulus can be defined for every thickness change in the blood vessel for any portion in the vessel's perimeter (see English translation of document p. 1-6 of attached NPL). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the limitations/steps of Hasegawa to provide a more accurate characterization of a diseased vessel with a non-uniform diameter.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIGEL FONTENOT whose telephone number is (571)270-7032. The examiner can normally be reached on Monday-Friday (7:00a-4:00p).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. F./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768